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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/595,096 | 06/15/2000 | David J. Diller | 1073.060 | 8927 |

23405 7590 12/17/2003

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER

MORAN, MARJORIE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/595,096

Applicant(s)

DILLER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/29/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

All rejections and objections not reiterated below are hereby withdrawn.

Information Disclosure Statement

The IDS filed 9/29/03 has been considered in full.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are again rejected, as previously set forth in the office action of 5/16/03, under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant's arguments filed 9/24/03 have been fully considered but they are not persuasive. Applicant argues that the claimed method may be used to aid in rational drug design, and that the concrete, tangible and useful result produced is "the three-dimensional structure of the ligand-receptor complex". In response, it is noted that the claims do not recite a receptor, and in fact, are directed to a method of docking, not to a method of modeling ligand-protein complexes. Further, as no specific protein or receptor is recited in the claims, the claims are not, in fact, directed to "rational drug design". In order to design a drug with any expectation of usefulness, one must start with a known correlation between a protein and a disease or disorder, such that one skilled in the art would reasonably expect an inhibitor, activator, agonist, antagonist, etc.

of the protein to affect the symptoms, course, or degree of severity of the disorder or disease. As no particular protein is recited in the claims, there is no correlation with a disease or disorder such that the claim method can be interpreted to be one of "rational drug design." In the absence of a recitation of a specific protein and/or any correlation with a known disease or disorder associated with either a protein or ligand, the results of the claimed docking method do not provide a concrete, tangible and useful result, therefore the examiner maintains that the claims are not statutory, and the rejection is maintained.

Claims 11-20 are directed to a "computer-aided system" comprising "means" for performing various acts, wherein the acts appear to be those of mathematical manipulation. No physical or "hardware" limitations are recited in claims 11-20, therefore it does not appear that the claimed "system" is a physical product, but is merely a listing of computer-implemented steps; i.e. a computer program. A computer program, per se, is not statutory subject matter. Applicant has not amended the claims to overcome this rejection nor presented arguments with to claims directed to computer programs, therefore the rejection is maintained.

Applicant is again reminded that claims 21-30, directed to computer-readable medium comprising a program, is directed to statutory subject matter, and is not rejected herein.

Claims 1-30 are again rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed to a method, and a "system" and program for performing the method, for docking a ligand to a protein. The claims do not recite any steps of identifying ligands, any particular proteins to which a ligand is docked, or any other "result" of the method, as set forth above.

Applicant's arguments filed 9/24/03 have been fully considered but they are not persuasive. Applicant argues that the claimed method may be used to aid in rational drug design, and that the concrete, tangible and useful result produced is "the three-dimensional structure of the ligand-receptor complex". Applicant argues that as the invention produces a tangible, concrete and useful result, it has a practical utility and "real-world" value. However, as previously set forth and reiterated above, the instant claims do not recite any particular protein for which ligand binding/docking is evaluated. The claims do not recite any selection, screening, identification ,etc. steps for any set of ligands docked to a protein. As previously set forth, a method of identifying or designing a receptor for a ligand with a known function (utility) would have utility under 35 USC 101. However, the claims do not recite any particular ligands, and do not recite any steps of identification or design of either a ligand or a receptor.

Applicant further argues that "the structures obtained" from the invention are valuable/essential in rational drug design. In response, it is noted that no actual structures are recited in the claims. If the receptor/ligand protein is not identified, then any "structures" resulting from the method are merely clusters of atomic coordinates or

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designations of energy states for which no use or function is known. As the claimed methods and products do not provide any "immediately useful benefit" to the public, the examiner maintains that the claims lack utility, and maintains the rejection.

Applicant's attention is directed to the Trilateral Project WM4, Vienna, Australia (November 4-8, 2002), found at www.uspto.gov, for a discussion of statutory considerations and utility with regard to *in silico* screening methods and examples of claim language and limitations which meet the requirements of both 35 USC 101 and 35 USC 112.

Conclusion

Claims 1-30 are again rejected.

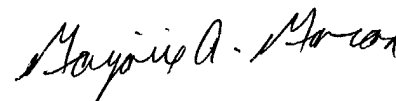
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363 until January 12, 2004. After that date, the telephone number will be (571)272-0720. The examiner can normally be reached on Monday to Wednesday, 7:30 am to 4 pm EST, Thursday, 7:30 am to 6 pm EST, and Friday, 7 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.



MARJORIE MORAN
PATENT EXAMINER

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